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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,728	06/27/2005	Thomas Julius Borody	119381-00002 / 3703US	7029

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EXAMINER	
HOLT, ANDRIAE M	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,728	BORODY ET AL.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 34-39* is/are pending in the application.

4a) Of the above claim(s) *3,12-18 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed June 26, 2009. Claims 1-18 and 34-39 are pending in the application. Claim 1 has been amended. Claims 12-18 and 34-36 have been withdrawn in the previous actions. Claims 1-11 and 37-39 will presently be examined to the extent they read on the elected subject matter of record.

Status of the Claims

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

New Rejection Necessitated by Amendment filed June 26, 2009

Claims 1-11 and 37-39 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kawakami (JP 05306221) in view of Colliopoulos (US 5,232,699) in further view of Cockerill (US 4, 452,779).

Applicant's Invention

Applicant claims a composition comprising at least one water-soluble sodium salt; at least on water-soluble minimally degradable sugar, at least on water-soluble potassium salt and at least on water-soluble magnesium salt. Applicant claims the minimally degradable sugar is xylose. Applicant further claims the water-soluble sodium salt is sodium chloride, the water soluble potassium salt is potassium chloride and the water-soluble magnesium salt is magnesium sulfate.

Determination of the scope of the content of the prior art (MPEP 2141.01)

Kawakami teaches an intestinal tract penetrant remover solution which contains 32.3 to 35.7 gm of magnesium citrate (magnesium salt, magnesium citrate 0.1 to 10 times weight of sodium salt, instant invention) in 900 ml of an aqueous solution of sodium chloride 4.8 to 5.4 mmol (sodium salt, sodium chloride, instant invention), potassium hydroxide 8.5 to 9.3 mmol (potassium salt, 0.05 to 1 times weight of sodium salt, instant invention) and sugars 10.7 to 2.1 gm (sugar, 1 to 3 times the weight of sodium salt, instant invention). Kawakami teaches the composition has a final osmotic pressure of 290 to 310 mOsm/L. Kawakami teaches that osmotic pressure in the range

of 290 to 310 mOsm/L is an osmotic pressure range which can be used safely and effectively as an intestinal tract penetrant remover without producing both absorption of moisture by body fluid and drying from the body fluid from an intestinal tract. Kawakami teaches the composition is used for intestinal diagnosis such as colonic endoscopy and x-ray graphy (method of inducing purgation of the colon, instant invention). Kawakami teaches the composition show similar rinsing effect as isotonic magnesium citrate solution and causes no electrolyte imbalance (Abstract).

Kawakami teaches in the example the preparation of the intestinal tract penetrant solution. Kawakami teaches that disintegration of the mixed liquor is dried and carried out and that 290 kg of dry articles are obtained. Kawakami teaches that 102.8 kg of white soft sugar is added to the obtained powder. Kawakami further teaches the mixture is filled up to 50 gm per bundle with an automatic filling machine. Kawakami teaches that it is the osmotic pressure about 300 mOsm/L which dissolved the pharmaceutical preparation at 50 gm per 1 bundle in water, and was set to 900 mL, in spite of the content of potassium ion and chloride ion.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Kawakami does not teach the minimally degradable sugar is xylose of claims 2 and 37-38. Kawakami does not teach the purgative comprises a hypertonic aqueous solution of claim 8. Kawakami also does not teach the water-soluble magnesium salt is magnesium sulfate of claim 38.

Colliopoulos teaches laxative compositions containing sennosides and psyllium, wherein sennoside is dispersed in a palatable food grade fat having a melting point

within the range of from about 30º C to about 50 º C., and to methods for treating constipation by ingesting compositions of the present invention (Abstract). Colliopoulos teaches optional components suitable for ingestion include: other dietary fiber (especially insoluble dietary fiber); shortening; flour; sweetening agent; and flavoring agent (col. 2, lines 62-65). Colliopoulos teaches the sweetening agents include water-soluble sweetening agents such as monosaccharides, disaccharides, and polysaccharides such as xylose, ribose, glucose, mannose, galactose, fructose, dextrose, sucrose, maltose, partially hydrolyzed starch or corn syrup solids and sugar alcohols such as sorbitol, xylitol, mannitol and mixtures thereof (col. 6, lines 51-61).

Cockerill teaches a composition comprising a combination of diuretic and cathartic components in proportions which maintain the electrolyte balance so as to avoid dehydration of the mammal while effectively removing excess fluid from mammary tissue via the kidneys and the intestinal tract and which in a preferred form is comprised on a weight basis of 65 percent sodium sulfate, 13 percent magnesium sulfate monohydrate, 12 percent sulfur and 10 percent anhydrous potassium sulfate (Abstract).

Cockerill teaches a suitable saline cathartic or laxative component can be selected from the group comprising potassium sulfate, potassium chloride, sodium sulfate, sodium chloride, sodium phosphate, sodium tartrate, sodium citrate, magnesium sulfate (claim 38, magnesium sulfate, instant invention) magnesium phosphate, magnesium oxide, magnesium hydroxide, magnesium tartrate, and magnesium carbonate (col. 2, lines 19-25). Cockerill teaches the compounds which

are less readily absorbed are preferred for use as the saline cathartic component of the composition and for providing a hypertonic solution in the intestinal tract (col. 2, lines 25-29). Cockerill teaches the saline cathartics preferably form a hypertonic solution in the intestine and the water draining into the intestine by osmotic pressure significantly increases the liquid bulk within the intestine which has an effect similar to other bulk cathartics or laxatives (col. 2, lines 29-34) (claim 8, hypertonic aqueous solution, instant invention). Cockerill further teaches where a large amount of a bulking agent is used in combination with the composition the amount of the cathartic used in the composition can be reduced (col. 2, lines 34-37). Cockerill teaches the magnesium sulfate, while having saline laxative properties, is used primarily as a source of magnesium to prevent hypomagnesia which otherwise would result due to the diuretic effect of the sodium sulfate and potassium sulfate components of the composition (col. 3, lines 28-33)

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Kawakami, Colliopoulos, and Cockerill and use xylose as the minimally degradable sugar in the composition. One skilled in the art at the time the invention was made would have been motivated to use xylose as the minimally degradable sugar because Colliopoulos teaches that xylose, glucose, and fructose are used as sweetening agents in laxatives. Therefore, the skilled artisan would have been motivated with a reasonable expectation of success to use xylose in the

composition as taught by Kawakami at the same ratios because xylose, glucose, and fructose are functionally equivalent sweetening agents for laxative compositions.

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Kawakami, Colliopoulos, and Cockerill and use magnesium sulfate as the water-soluble magnesium salt in a hypertonic solution. One skilled in the art at the time the invention was made would have been motivated to use the magnesium sulfate because Cockerill teaches that magnesium sulfate while having saline laxative properties, is used primarily as a source of magnesium to prevent hypomagnesia which otherwise would result due to the diuretic effect of the sodium salt and potassium salt components of the composition.

One skilled in the art at the time the invention was made would also have been motivated to produce a hypertonic solution with a reasonable expectation of success as Cockerill teaches saline cathartics, magnesium sulfate, preferably form a hypertonic solution in the intestine and the water draining into the intestine by osmotic pressure significantly increases the liquid bulk within the intestine which has an effect similar to other bulk cathartics or laxatives. Given the state of the art as evidenced by the teachings of the cited references, and absent any evidence to the contrary there would be a reasonable expectation of success in combining the teachings of the cited references to produce a good tasting laxative composition that can be used safely and effectively as purgative without depleting the body of essential electrolytes, causing dehydration and other side effects associated with electrolyte purgative.

In reference to the weight ratios and the unit dose formulations, the adjustment of particular conventional working conditions (e.g., weight ratios and unit dose formulations) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Response to Arguments

Applicant's arguments filed June 26, 2009 have been fully considered but they are not persuasive. Applicant argues Kawakami does not teach or suggest a composition that includes at least one water-soluble minimally degradable sugar and that the supporting references Colliopoulos and Cockerill fail to teach or suggest the elements missing from the combination, at least one water-soluble minimally degradable sugar, particularly xylose, a composition that includes a minimally degradable sugar at the required ratio to sodium salt, and a composition that is a hypertonic aqueous solution.

In response to Applicant's arguments, Kawakami teaches the saccharide contains sugar types having sweetness, for instance, sucrose, maltose, grape sugar, invert sugar, and the like. Because Kawakami teach that sugar types having sweetness can be used it would have been obvious to the skilled artisan to try any one of the

sweeteners taught in the Colliopoulos reference, including xylose, glucose, and fructose. It would have been obvious to the skilled artisan to use either of the sweetening agents as these are common sweetening agents used in laxative compositions as evidenced by Moskowitz, US Patent No. 4,766,004, which is incorporated by reference in Colliopoulos, and Andre et al., US Patent No. 5,173,296. Moskowitz teaches that sweetening agent ingredients used in the compositions include water-soluble sweetening agents such as monosaccharides such as xylose, ribose, glucose, fructose, and sucrose (col. 5, lines 53-56). Andre et al. teach compositions that provide laxation and regulating bowel function (col. 3, lines 7-12). Andre et al. teach the compositions comprise a sweetening agent that includes water-soluble sweetening agents such as xylose, ribose, glucose, fructose and sucrose. As such, the skilled artisan would have been motivated at the time of invention to make the substitution because as evidenced by the prior art, these sweeteners are known to be used in as sweetening agents in laxative compositions.

Applicant also argues that there is no teaching or suggestion that using a minimally degradable sugar in a purgative composition avoids gas formation, bloating or cramps that can be caused by the fermentative breakdown of degradable sugars. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., purgative composition avoids gas formation, bloating or cramps that can be caused by the fermentative breakdown of degradable sugars) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from

the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the combination of the references relies on the improper use of hindsight. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As such, the skilled artisan would have been motivated to combine the cited references to produce a good tasting laxative composition that can be used safely and effectively as purgative without depleting the body of essential electrolytes, causing dehydration and other side effects associated with electrolyte purgative as taught in the prior art.

Response to Declaration

The declaration under 37 CFR 1.132 filed June 26, 2009, is insufficient to overcome the rejection of claims 1-11 and 37-39 based upon 35 U.S.C. 103(a) as set forth in the Office action because: the data is not commensurate in scope with the claims and there is no difference in kind between the claimed invention and the comparison data (prior art). Applicant claims a composition comprising at least one

water-soluble sodium salt, at least one water-soluble minimally degradable sugar, at least one water-soluble potassium salt, and at least one water soluble magnesium salt. Applicant provides data for the "hypertonic solution" that includes xylose, magnesium sulphate, sodium chloride, sodium citrate, and potassium gluconate. The components of "hypertonic solution" are single species in the genus of water-soluble sodium salts, water-soluble minimally degradable sugars, water-soluble potassium salts and water-soluble magnesium salts. The examiner cannot determine if the results obtained would be representative of the results using any water soluble sodium salt, water-soluble minimally degradable sugar, water-soluble potassium salt, and water soluble magnesium salt. A single species cannot show purported unexpectedness of an entire genus. Therefore, the examiner cannot determine based on a single species that has been tested, if the entire genus would produce the purported unexpected results. Therefore, the examiner notes that the claims are not commensurate in scope.

The efficacy data provided demonstrates that doctors and sedationists did not significantly differentiate between the different bowel preparations in the overall adequacy of bowel cleansing. The doctors and sedationists did agree that HYPC (applicant's invention) was more effective in cleansing the transverse colon than the other bowel preparations. However, that is only one section of the colon that showed a significant difference (page 36, Efficacy). The safety data suggests that approximately half of the subjects in the HYPC arm experienced side effects that were possibly related to the bowel preparation. However, the data suggest the PS (prior art) results in fewer side effects, but PCA (prior art) resulted in milder side effects. HYPC and PCA do not

cause any significant clinical changes in laboratory results (page 36, Safety). In the conclusions section, the findings indicate that overall, PCA were most favored as a bowel preparation by subjects, and in general, resulted in a lower number of mild adverse events than the other preparations. However, doctors and sedationists generally rated the efficacy of HYPC and PS (prior art) as more effective than the other preparations in cleansing the bowel (page 37, Conclusions). Based on the data HYPC, Applicant's invention, does not provide any unexpected or superior results when compared to the prior art (PCA or PS), thus no difference in kind.

None of the claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/John Pak/
Primary Examiner, Art Unit 1616